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#5  
Docket No. VAS-5041DIV2

**Certificate of Mailing/Transmission (37 C.F.R. § 1.8(a)):**

[X] Pursuant to 37 C.F.R. § 1.8, I hereby certify that this paper and all enclosures are being deposited with the United States Postal Service as first class mail on the date indicated below in an envelope addressed to the Assistant Commissioner for Patents, Washington D.C. 20231.

[ ] Pursuant to 37 C.F.R. § 1.6(d), I hereby certify that this paper and all enclosures are being sent via facsimile on the date indicated below to the attention of Examiner \_\_\_\_\_ at Facsimile No. \_\_\_\_\_ at \_\_\_\_\_ a.m./p.m.

Dated: February 14, 2003

Name of Person Certifying:  
Printed Name:

*Melissa Sanchez*  
Melissa Sanchez

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**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Applicant: Donald T. Shannon et al.

Assignee: Edwards Lifesciences LLC

Filing Date: October 16, 2001

Examiner: Brian E. Pellegrino

Serial No.: 09/981,337

Group Art Unit: 3738

Title: RADIALLY EXPANDABLE STENTED TUBULAR PTFE GRAFTS

**RESPONSE TO RESTRICTION REQUIREMENT**

Assistant Commissioner for Patents  
Washington, D.C. 20231

Dear Sir:

This is in response to the restriction requirement set forth in the Office Action, dated November 14, 2002, in the above-identified patent application.

The Examiner identified the following species in the Office Action:

**Forms of Stented Graft:**

- I. Integrally stented PTFE graft
- II. Internally stented PTFE graft
- III. Externally stented PTFE graft

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**Application of Polymer Coating:**

- 1) immersion in a liquid polymer
- 2) electron beam deposition

3) polymer tube placed around elongate members

Type of Stent:

Species A: self-expanding

Species B: pressure-expandable

Applicants provisionally elect with traverse the following species, and request reconsideration of the restriction requirement:

Internally stented (II) self-expanding stent (Species A) and application of polymer coating is by placing a polymer tube around elongate members (3). Claims 1-21, 24-34, and 37-40 are readable thereon.

Applicants respectfully submit that claims for an integrally stented graft, an internally stented graft and an externally stented graft do not constitute three independent and distinct inventions. Independent claim 1 describes a stent that has on its outside surface a tubular elastomer covering. Independent claim 41 describes a stent that has on its inside surface a tubular elastomer covering. Independent claim 71 describes a stent that has elastomer coverings on both its inside and outside surfaces. Thus, independent claim 71 is related to claim 1 or 41 in that it only contains additional limitations to those of either independent claim 1 or 41. Applicants respectfully submit that a restriction between these "species" is not supported by the law.

The Commissioner may require restriction if two or more independent and distinct inventions are claimed in one application. 35 USC section 121. Furthermore, if the search and examination of an entire application can be made without serious burden, the examiner must examine it on the merits, even though it includes claims to independent or distinct inventions. MPEP section 803. Thus, a restriction requirement is proper only when both of the following conditions are met: (1) the inventions are independent or distinct; and (2) there is a serious burden on the Examiner if restriction is not required. Id.

As the above shows, the inventions of so-called species are not independent. Furthermore, any restriction requirement must be accompanied by a showing as to why restriction is necessary. If there is a serious burden on the Examiner, the Examiner should

provide an appropriate explanation, i.e., either separate classification, separate status in the art, or a different field of search. MPEP 803. Applicants respectfully submit that the Examiner has failed to do so. The elected claims are directed to stents with elastomer coverings and, therefore, separate and distinct searches for the claims will not be necessitated.

For the foregoing reasons, Applicants request the Examiner to withdraw the restriction requirement with respect to species I, II and III.

#### **PETITION FOR EXTENSION OF TIME TO RESPOND**

Pursuant to 37 C.F.R. 1.136(a), Applicants hereby request an extension of time for **Two Months** to respond to the above-referenced Office Action. The Commissioner is hereby authorized to charge the required fee of \$410.00 to Deposit Account No. 50-1225 (Docket No. VAS-5041DIV2). A duplicate copy of this sheet is enclosed.

#### **CONCLUSION**

For the foregoing reasons, Applicants respectfully request reconsideration and withdrawal of the restriction requirement as to election of species between species I, II and III.

If an appropriate payment does not accompany or precede this submission, the Commissioner is hereby authorized to charge any required fees, such as under 37 C.F.R. §§ 1.16 or 1.17, including any petition for extension of time, or to credit any overpayment, to Deposit Account No. 50-1225.

Respectfully submitted,



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Registration No. 43,999

Edwards Lifesciences LLC

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Dated: February 14, 2003

**Customer No.: 30452**